

REMARKS

By an Office Action dated April 8, 2004 in the file of this application, the Examiner rejected the pending claims of the application based on a variety of objections. In response to that Office Action, the applicants have amended the claims and presented these remarks.

The applicants acknowledge that the Examiner has made the restriction requirement final.

The Examiner has required the applicants to note that certain words were trademarks. That has been done in the specification.

In a claim objection, the Examiner found a misspelling in Claim 11. That has been corrected.

The claims of the application under examination were rejected under 35 U.S.C. §112, first paragraph, on the grounds that the application was enabling for method of diagnosing obesity in mice, but argued that the method described herein does not provide a method for enabling a diagnosis of diabetes or susceptibility of diabetes. The applicants respectfully traverse this ground of rejection.

The mouse models used here are a normal animal model used to be a predictive disease model for diabetes. It is well known that the phenomenon of increasing insulin resistance is a trait of individuals who are susceptible to, or are in the process of becoming, Type II diabetics. The present invention was a result of a methodology specifically designed to discover what gene expression patterns were associated with the onset of insulin resistance, and therefore the onset of and susceptibility to Type II diabetes. While the work was done on mice, this mice model is a commonly used model for the progression from normal individual to insulin insensitive diabetes. This methodology and the reason for using this animal model was carefully set forth in the specification and accepted by those of ordinary skill in the art.

Also as is taught in the specification, a particularly significant gene for the progression to diabetes is the gene referred to as SREBP. The gene encodes a protein transcription factor regulating genes for lipogenic enzymes (Paragraphs [00019] and [00039] of the specification). As the specification states clearly, it is the current belief in the art that a change in lipogenic capability in adipose tissues is indicative of a change to insulin resistance (paragraph [00021]). It is therefore asserted that the claims of the present application are properly constructed. Nevertheless, to help obviate this objection, all of the claims have been altered to make it clear that a “susceptibility to diabetes” or a “transition from obese to diabetic” is the object of each of each of the methods of the claims of the present invention. It is submitted that these methods, exemplified by the SREBP gene, and the other three genes

claimed which are closely associated with it, are commensurate with the scope of what the applicants have enabled by this application. Accordingly, reconsideration of the merits of this rejection is respectfully requested.

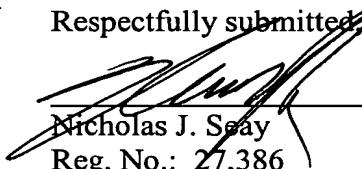
The second ground of rejection was under 35 U.S.C. §112, second paragraph, for indefiniteness. The applicants also respectfully traverse that rejection. The claims as presently written are specific to a Markush group of four specific genes. In each claim it is specifically recited that the expression pattern of the gene decreases if the individual has cells progressing toward diabetes or is susceptible to diabetes. It is asserted that this is the proper scope of the invention as enabled by the applicants here.

Lastly, Claim 5 was rejected under 35 U.S.C. §103. The Examiner argued that because the claims could be read on any gene, the prior art showing a different gene associated with diabetes was relevant prior art. Since the claims are clearly now restricted to four specific genes claimed as a Markush group, this prior art is no longer relevant. Accordingly it is believed that this rejection is also improper.

Wherefore, a reconsideration on the merits of this application is respectfully requested.

A separate petition for extension of time is submitted herewith so that this response will be considered as timely filed.

Respectfully submitted,



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